



Leader in scientifically proven
essential fatty acid supplements
for over 25 years

January 12, 2005

Office of Nutritional Products
Labelling and Dietary Supplements (HFS-810)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Pkwy
College Park, MD 20740

JAN 14 2005

RE: CLAIMS NOTIFICATION

a) Name and Address of the Manufacturer

Efamol Ltd.
Brackenholme Business Park
Brackenholme, Selby
North Yorkshire
YO8 6EL
United Kingdom

b) Text of the Statement that is being Made

B-1 – For Healthy Skin

People with healthy skin have normal blood levels of the essential fatty acid, linoleic acid and all the omega 6 fatty acids derived from it including gamma-linolenic acid (GLA). These fatty acids help create an effective barrier in the skin to reduce water loss and maintain overall skin condition and integrity including firmness, elasticity, strength and smoothness. In addition, prostaglandins and other metabolites derived from these fatty acids modulate normal skin structure and function. Supplementing the diet with Efamol® Evening Primrose Oil ensures an intake of GLA that helps maintain healthy skin.*

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

B-2 – For Mild Menstrual Related Symptoms

Many women experience little or no discomfort, mild mood changes, bloating or breast tenderness associated with their menstrual cycle. These women also have normal levels of polyunsaturated fatty acids (PUFAs) in their bodies which may help control typical responses to circulating hormones. Supplementing the diet with Efamol® Evening Primrose Oil ensures an intake of PUFAs that supports a normal, healthy attitude during premenstrual syndrome (PMS).*

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B-3 – For Nerve Function

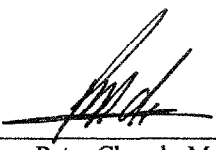
Fatty acids including gamma-linolenic acid (GLA) and other substances derived from it are important in nerve structure and function. They are part of the myelin sheath, the protective insulation that surrounds all nerve fibers and enables them to transmit impulses correctly. In addition, prostaglandins and other regulatory substances derived from these fatty acids help control blood flow around nerves ensuring the supply of vital nutrients. Nerve function can be assessed by measuring ability to detect skin temperature changes (hot and cold), muscle strength and reflexes, and how fast nerves can send messages. Supplementing the diet with Efamol[®] Evening Primrose Oil ensures an intake of GLA that helps maintain healthy nerve function.*

* These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

c) **The Name of the Dietary Supplement that is the Subject of the Statement**
Efamol[®] Evening Primrose Oil

d) **Certification**

I, Peter Clough, certify the accuracy of the information presented and contained in this notice, that the information contained in the notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

Signature: 
Peter Clough, Managing Director, Efamol Ltd.

Date: January 12 2005